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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,802	08/25/2003	Bijan S. Khirabadi	102691.02	1323

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EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/646,802	Applicant(s) KHIRABADI ET AL.	
	Examiner Sandra Saucier	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/25/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1–25 are pending and are considered on the merits.

Election/Restriction

Applicants' arguments concerning the restriction requirement are persuasive. The requirement has been removed and all claims are under examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1–25 are rejected on the ground of nonstatutory obviousness–type double patenting as being unpatentable over claims 13–15 of U.S. Patent No. 6,194,137 [IDS]. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope. While the claimed methods of vitrification and devitrification in US 6,194,137 are limited to blood vessels, the instant claims encompass this element because they are directed to vitrification and devitrification methods of tissues and organs. Blood vessels may be considered to be an organ or a tissue and are also specifically claimed in the instant claim 18.

Please amend Claim 1, line 10 to read “the tissue or organ” as this recitation has antecedent basis in the claim.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1–25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,559,298 [IDS].

The claims are directed to The claims are directed to a method of removing a vitrified tissue or organ from a vitrification solution which contains cryoprotectant comprising:

warming the vitrified organ at a rate less than 50C/min to a temperature between the Tg of the solution and –80C, further warming the tissue or organ at a rate greater than 80C/min to a temperature above –75C, which

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temperature results in the solution being sufficiently fluid that the organ/tissue can be removed therefrom,

immersing the tissue/organ in a series of solutions having decreasing concentrations of cryoprotectant to obtain the tissue/organ in a cryoprotectant-free solution.

The references are relied upon as explained below.

US 4,559,298 discloses a method of removing an organ (kidney) from vitrification comprising warming very slowly to near T_g to prevent fracture, then warming as fast as possible to T_m , in order to avoid crystallization as much as possible, then reducing the concentration of cryoprotectants by perfusing with solutions containing a lower concentration of cryoprotectants until all cryoprotectants are removed (col. 8, ls. 35–45).

In the discussion in col. 7, a critical warming rate achievable for kidneys is about 100C/min. The critical warming rate is the rate between the T_c where the solution may crystallize and T_m where the solution becomes liquid.

Thus, this reference teaches warming slowly to near T_g , then rapid warming to elevate T_c and to achieve T_m . Figure 3 diagrams the upward shift in T_c with increasing warming rates. Thus, this reference teaches a second step of warming of at least 100C/min, and a first step of slowly warming to near T_g in order to remove organs from vitrification with retention of function. The cryoprotectant concentration is gradually reduced to zero with the addition of an osmotic antagonist such as mannitol. The process of vitrification is done with stepwise increasing concentrations of cryoprotectants (col. 8, l. 6–15) in two stages of cooling, a first stage as quickly as possible to below T_g , a slower rate of 0.5C/min to about -140 C.

The reference appears to lack the specific first warming rate of less than 50C/min, the use of six solutions to bring the concentration of cryoprotectant to zero and the use of a cooling rate 2.5–100C/min.

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The use of a first warming rate of less than 50C/min and the use of a cooling rate of 2.5–100C/min would have been obvious because the reference teaches a first warming step described as “slowly” warming and a first cooling step “as quickly as possible”.

This is considered to be an optimization of ranges through routine experimentation. See MPEP 2144.05 II. A.

The use of a continuous washout of cryoprotectants or a step wise decrease is considered to be obvious because a process may either be step-wise (batch) or continuous and achieve the same end point in the absence of evidence of criticality. See MPEP 2144.04 V.E.

Claims 1–22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pegg et al. [U] in combination with US 5,962,214 [IDS].

Pegg et al. disclose a method of removing an organ (artery) from vitrification comprising warming slowly (40–60C/min) between the storage temperature (–180C) and –140C to –100 C (T_g is –123C) to prevent fracture, warming more rapidly (beginning at 200C/min, at 15 seconds the rate is 50–80C/min) to 37C with removal of the cryoprotectant, abstract and pages 187–188. The reference also teaches cooling the artery after the final cryoprotectant concentration has been reached @ 1C/min to storage temperature. The reference lacks the explicit disclosure of decreasing concentrations of cryoprotectant during removal of the artery from vitrification.

US 5,962,214 discloses a method of removing an organ from vitrification comprising perfusing and or superfusing (col. 6, l. 6) the organ with decreasing the concentrations of cryoprotectant in a stepwise fashion (col. 6, l.45).

The addition of the dilution protocol discussed in US 5,962,214 to the warming protocol of Pegg et al. would have been obvious because Pegg et al. in the abstract disclose stepwise addition and subsequent removal of the cryoprotectant and US 5,962,214 teach that stepwise removal of cryoprotectant

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from a cryopreserved tissue/organ gives superior results in terms of viability of the organ/tissue.

Claims 23–25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pegg et al. [U] and US 5,962,214 [IDS] as applied to claims 1–22 above, and further in view of US 4,559,298 [IDS].

The claims are further directed to steps of cooling an organ/tissue which has a vitrifiable concentration of cryoprotectant with a two step protocol of 2.5–100C/min from a temperature above –15C to a temperature between –80 and Tg, and further at a rate of less than 30C/min to a temperature below Tg.

US 5,962,214 discloses using “appropriate protocols” to cool and vitrify organs with or without application of pressure (col. 34, l. 65).

US 4,559,298 discloses a method of cryopreservation comprising increasing the concentration of cryoprotectant to the vitrification concentration, decreasing the temperature as quickly as possible to below Tg, (cooling rates of 10/min are easily attainable, col. 5, l.43) then more slowly decreased at a rate of 0.5C or less/min (col. 8, l. 20–25).

The substitution of the cooling protocol of US 4,559,298 in the method of removing an organ from vitrification as disclosed by Pegg et al. and US 5,962,214 would have been obvious because use of this cooling protocol prevents cracking of the glass (col. 8, l. 23) formed in the process.

One of ordinary skill in the art would have been motivated at the time of invention to make these additions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

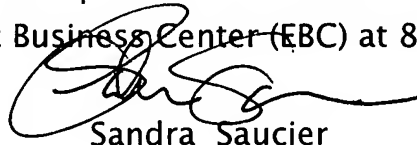
Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier

Primary Examiner

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March 8, 2006